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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,813	10/19/2004	Johannes Coy	4007.008	6538

41288 7590 12/08/2005

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,813	COY, JOHANNES	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-6, 8-10, and 17-20, as specifically drawn to the "special technical feature" of detecting the presence or absence and/or the level of expression of human transketolase like-1 gene at the *protein level* and kits used to detect the presence or absence and/or the level of expression of human transketolase like-1 gene at the *protein level.*

Group 2, claim(s) 1-5, 7, and 11-20, as specifically drawn to the "special technical feature" of detecting the presence or absence and/or the level of expression of human transketolase like-1 gene at the *nucleic acid level* and kits used to detect the presence or absence and/or the level of expression of human transketolase like-1 gene at the *nucleic acid level.*

Group 3, claim(s) 21-27, as specifically drawn to the "special technical feature" of a method for treating disorders comprising administration of a pharmaceutical composition containing a human transketolase like-1 *polynucleotide*.

Group 4, claim(s) 21-27, as specifically drawn to the "special technical feature" of a method for treating disorders comprising administration of a pharmaceutical composition containing a human transketolase like-1 *polypeptide*.

Group 5, claim(s) 28, as specifically drawn to the "special technical feature" of use of a human transketolase like-1 *polypeptide* for the production of a pharmaceutical composition.

Group 6, claim(s) 28, as specifically drawn to the "special technical feature" of use of a human transketolase like-1 *polynucleotide* for the production of a pharmaceutical composition.

Group 7, claim(s) 29, drawn to the "special technical feature" of a method of identifying and obtaining a drug candidate for therapy.

Group 8, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition identified by the method of Group 7.

Group 9, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition comprising an antithiamine compound.

Group 10, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition comprising an inhibitor of transketolase enzyme activity.

Group 11, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition comprising an inhibitor of transketolase like-1 activity.

Group 12, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition comprising a transketolase like-1 polypeptide.

Group 13, claim(s) 30 and 33, as specifically drawn to the "special technical feature" of a pharmaceutical composition comprising a human transketolase like-1 nucleic acid.

Group 14, claim(s) 31-32, as specifically drawn to the "special technical feature" of a method for reducing transketolase like-1 activity in individuals comprising administering antithiamine compounds.

Group 15, claim(s) 31-32, as specifically drawn to the "special technical feature" of a method for reducing transketolase like-1 activity in individuals comprising administering pharmaceutical composition identified by the method of Group 7.

Group 16, claim(s) 31-32, as specifically drawn to the "special technical feature" of a method for reducing transketolase like-1 activity in individuals comprising administering inhibitors of transketolase enzyme activity.

Group 17, claim(s) 31-32, as specifically drawn to the "special technical feature" of a method for reducing transketolase like-1 activity in individuals comprising administering transketolase like-1 antisense constructs and a method for reducing transketolase like-1 activity in individuals comprising administering ribozymes specific for transketolase like-1.

Group 18, claim(s) 31-32, as specifically drawn to the "special technical feature" of a method for reducing transketolase like-1 activity in individuals comprising administering thiamine.

The inventions listed as groups 1-18 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: groups 1-18 encompass different special technical features as identified in the groupings above. Then inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different *categories* of inventions unity of invention will only be found to exist if specific combinations of inventions are present.

The allowed combinations do not include multiple products and multiple method of using said products, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. The instant groups attempt to link products with the special technical feature of using said products in various methods. However, the products themselves do not share significant structural elements to the extent that each member could be substituted, one for the other, with the expectation that the same intended results would be achieved. Since multiple products and multiple methods with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, se PCT article 7(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Accordingly, groups 1-18 are not so linked to form a single inventive concept and restriction is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

The diseases listed in claims 3 and 25 are listings of distinct **species of cancers** (colon cancer, lung cancer, gastric cancer, or pancreatic cancer). Further, the tumors listed in claims 29 and 30 represent distinct **species of tumors** (tumors of the colon, the lung, the pancreas, or the stomach). Further, the biological samples listed in claims 4 and 5 represent distinct species of **sample types** (body fluid, secretions, smears, biopsys, liquid containing cells, lysed cells, cell debris, peptides, nucleic acids, serum, urine, semen, stool, bile, cell sample, tissue sample). Each species of cancer and each species of tumor represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. For example, the above species of cancers differ at least in etiology, pathology, and mechanisms. Further, the various species of sample types represent samples that differ in methods of acquisition and protein and nucleic acid samples, for example, would require different methods of purification and analysis. As such, each species requires different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER